Remarks

Claims 1-3 and 8-11 are pending. Claims 2 and 3 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Upon entry of these amendments, claims 1 and 8-11 will be pending. No new matter enters by way of these amendments.

I. Status - Withdraw of Allowability

A Notice of Allowability of claims 1-3 and 8-11 was mailed on January 6, 2004. However, a Notice of Withdrawal from Issue was mailed on February 2, 2004 stating that "[T]he application is being withdrawn to permit reopening of prosecution." Applicants acknowledge that prosecution has been re-opened and additional grounds of rejection have been applied in the Office Action mailed March 12, 2004.

II. Rejection under 35 U.S.C. §101

Claims 1-3 and 8-11 stand rejected under 35 U.S.C. § 101 "because the claimed invention lacks a credible, substantial, specific or well-established utility." Office Action at page 2. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "to obtain other nucleic acids from the same species or to isolate homologous nucleic acids from other species." Office Action at page 3. The Examiner asserts that "[B]ecause a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a 'real world' context of use." *Id.* Moreover, the Examiner acknowledges that the specification describes other utilities for the claim invention such as use in "mapping

studies, linkage analysis, constructing of transgenic plants, screening for traits or screening for polymorphisms." *Id.* However, the Examiner contends that none of the utilities disclosed in the present application satisfy 35 U.S.C. § 101 because "[t]hese are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes." *Id.*

The "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, use to identify a polymorphism in a population of plants. *See, e.g.* Specification at page 49, line 24 through page 56, line 24. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification discloses several uses for the claimed nucleic acid molecules, including use as nucleic acid molecule markers and probes (*see, e.g.*, specification at page 40, line 25 through page 49, line 23); to identify and obtain nucleic acid homologues (*see, e.g.*, specification at page 39, line 11 through page 40, line 24); in microarrays as gene-specific targets (*see, e.g.*, specification at page 57, line 24 through page 59, line 10); to identify the presence or absence of a polymorphism (*see, e.g.*, specification at page 49, line 24 through page 56, line 24); use to transform plants (*see, e.g.*, specification at page 61, line 1 through page 77, line 22); to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule (*see, e.g.*, specification at page 56, line 25 through page 57, line 19); and use to

overexpress or suppress a desired protein (*see, e.g.,* specification at page 77, line 13 through page 80, line 8).

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed nucleic acid molecules possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating that "the disclosed uses are generally applicable to broad classes of this subject matter." Office Action at page 3. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That

position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid

molecules. The Examiner "must do more than merely question operability - [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

The Examiner also asserts that the claimed nucleic acid molecules lack utility apparently because "the specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein." Office Action at page 3. Applicants respectfully submit that the skilled artisan would be able to ascertain these activities based on Applicants' disclosure and tools available to practitioners in the art, *e.g.*, BLASTX. Furthermore, such activity is not necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in cosuppression/antisense applications. Although Applicants disagree with the Examiner's contention, to facilitate prosecution, claim 3 has been cancelled herein without prejudice to or disclaimer of the underlying subject matter.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26

U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

III. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-3 and 8-11 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 6.

Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

The Examiner also alleges that "the specification has not adequately taught one of skill in the art how to use nucleic acids that are capable of specifically hybridizing with the nucleic acid of SEQ ID NO: 1 or which comprise a nucleic acid which has 90%-100% identity with SEQ ID NO: 1. Applicants again respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

IV. Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 2-3 and 8-11 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at pages 6-7. Claims 2-3 have been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond as the rejection applies to claims 8-11. Applicants respectfully traverse this rejection.

The Examiner, acknowledges that "[n]ucleic acids consisting of SEQ ID NO: 1 and proteins encoded by SEQ ID NO: 1 meet the written description requirement." Office Action at page 7. However, the Examiner argues that Applicants have allegedly

not described "the claimed genus of nucleic acids that specifically hybridize with SEQ ID NO: 1 or which having [sic] 90-99% identity with SEQ ID NO: 1." *Id.* The basis for the Examiner's rejection is that "the claims include nucleic acids and proteins from other species, naturally-occurring and non-naturally occurring mutated nucleic acids, allelic variants, and splice variants and fragments of said nucleic acids." *Id.* at page 8. Apparently, the Examiner contends that "the specification does not exemplify any specific nucleic acids that ... have 90-99% identity with SEQ ID NO: 1." *Id.* In addition, the Examiner suggests that the use of the open claim language "having" includes "additional splice variants and homologues which differ significantly from SEQ ID NO: 1 in terms of their structure and function. " *Id.* at page 9. Applicants respectfully disagree.

It is well-established law that use of the transitional term "comprising" or "having" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are <u>not</u> specified or described. The Examiner attempts to turn the legal meaning of "having" on its head. The claims recite the required nucleic acid sequences and recite percent sequence identities. Applicants' amended claims do not recite proteins and, accordingly, need not describe them. Applicants need only describe the <u>claimed</u> invention, and have done so in the present application.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of nucleic acid molecules SEQ ID NO: 1, and sequences with the recited percent identity and therefore, the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.*, specification at page 23, line 5 through page 30, line 6; and page 49, line 24 through page 56, line 24). The specification also describes appropriate hybridization conditions (*see, e.g.*, specification at 19, lines 5-18); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.*, specification at page 32, line 5 through page 33, line 10); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 34, lines 18-24); nucleic acids comprising introns, intron/exon junctions, or both (*see, e.g.*, specification at page 33,

lines 11-19); plant homologue proteins (*see, e.g.,* specification at page 34, line 25 through page 35, line 13); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 59, line 11 through page 60, line 27); and vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.,* specification 61, line 1 through page 75, line 12). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the Examiner maintains that "the description of one molecule (SEQ ID NO: 1) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 1 having unspecified functional activities different from that of SEQ ID NO: 1." Office Action at page 9.

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description. For example, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 1, and complements and variants thereof. The respective common structural feature (*e.g.,* the nucleotide sequences of SEQ ID NO: 1 and their complements) is shared by <u>every</u> nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule

contains one of the recited nucleotide sequences. Thus, pending claims 8-11 is supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

V. Rejection under 35 U.S.C. §112, Second Paragraph

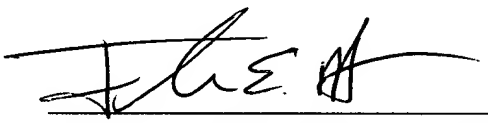
Claims 2 and 3 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 10.

Claims 2 and 3 are allegedly indefinite in the recitation of the phrase "capable of specifically hybridizing" because "[C]apability is a latent characteristic and the claims do not set forth the conditions under which the capacity to hybridize is to be determined." Office Action at page 10. Applicants respectfully disagree, however, in order to facilitate prosecution, claims 2 and 3 have been cancelled without prejudice to or disclaimer of the subject matter. As such, Applicants respectfully request that the Examiner withdraw this indefiniteness rejection.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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